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SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device: DSL 9100 IGF-II IRMA Kit
Classification Name: Immunoradiometric Assay, IGF-II
Analyte Code and Name: Insulin Like Growth Factor-II
Regulatory Class: I

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The DSL IGF-II IRMA kit was developed for the quantitative measurement of IGF-II in human serum or plasma. The IRMA format is a non-competitive assay in which the analyte to be measured is "sandwiched" between two antibodies. The first antibody, goat anti-IGF-II, is immobilized to the inside wall of the test tube, the other antibody, mouse monoclonal anti-IGF-II is radiolabelled for detection. The analyte present is bound by both the antibodies to form a "sandwiched" complex. Unbound materials are removed by decanting and washing the tubes. The resultant is analyzed in a gamma counter for bound counts per minute. The amount of bound IGF-II is directly proportional to the concentration of the IGF-II present in the sample.

The DSL IGF-II IRMA assay is intended for the quantitative determination of IGF-II in human serum or plasma. The measurement of IGF-II is used For *In Vitro* Diagnostic Use in the evaluation of growth status.

The DSL IGF-II IRMA is substantially equivalent to the DSL IGF-I IRMA.

Both assays are used in the evaluation of growth status with human serum or plasma samples.